

DEC 11 1990

MEMORANDUM FOR: Chairman Carr  
 Commissioner Rogers  
 Commissioner Curtiss  
 Commissioner Remick

FROM: James M. Taylor  
 Executive Director for Operations

SUBJECT: STAFF REVIEW OF THE MASSACHUSETTS DEPARTMENT  
 OF PUBLIC HEALTH (MDPH) LEUKEMIA STUDY AROUND  
 THE PILGRIM STATION

This transmits the staff review of the MDPH report on the incidence of leukemia in 22 communities near the Pilgrim plant during the period from 1978 through 1986. Although limited in scope for reasons stated in the enclosure, the staff's review could not find a justification for the reported correlation between radiation exposure and the increase in leukemia incidence. Specifically, the staff could find no support for any increase in leukemia incidence being linked with Pilgrim plant operation, much less the claim of a 400 percent increase.

The staff plans no further study of the MDPH report, but will monitor the results of reviews performed by health-oriented agencies such as NIH/NCI, among others.

Original Signed By  
 James M. Taylor

James M. Taylor  
 Executive Director  
 for Operations

2-26-91

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D. C. 20555

NOV 30 1990

MEMORANDUM FOR: Hugh L. Thompson, Jr.  
Deputy Executive Director  
for Nuclear Materials Safety, Safeguards,  
and Operations Support

FROM: Frank J. Congel, Director  
Division of Radiation Protection  
and Emergency Preparedness  
Office of Nuclear Reactor Regulation

SUBJECT: STAFF REVIEW OF THE MASSACHUSETTS DEPARTMENT OF  
PUBLIC HEALTH (MDPH) LEUKEMIA STUDY AROUND THE  
PILGRIM STATION

We have completed a limited review of the subject report, and have enclosed a summary of our findings. We confined our review to technical areas of staff expertise, including the evaluation of effluent releases, the calculation of associated environmental radiation doses, and the estimation of radiation risks. In addition, the National Cancer Institute (NCI) will probably conduct a detailed review of the epidemiological aspects of the report. We plan to follow the course of that review.

The MDPH report examined the incidence of leukemia in 22 communities near the Pilgrim plant from 1978 through 1986. The report claims that, among people most highly exposed to effluents from the Pilgrim plant, an increase in leukemia risk of up to 400 percent occurred between 1978 and 1983, but that no increase was noted from 1984 through 1986. The MDPH report states that the increase could be due to radiation exposure from the Pilgrim plant but acknowledges that direct causality has not been proven.

Our review resulted in several findings. First, the MDPH researchers used an inaccurate method of determining relative exposures. Second, the incidence of leukemia commonly varies with time and place. Third, radioactive releases from Pilgrim have been far too small to cause any discernible increase in leukemia incidence. Furthermore, an increase in leukemia incidence in one 5-year interval followed by a return to normal incidence in subsequent years is not consistent with a radiation-induced increase. Thus, the correlation in the MDPH study between radiation exposure and the increase in leukemia incidence does not appear to be justified.

We did not perform a detailed review of the MDPH study. The principal reasons for this are that the report does not include the basic data required for such an evaluation, and a detailed review of the MDPH study would involve subject matters such as epidemiology and biostatistics, which are outside our general areas of expertise. We did not contract for such expertise because we were not convinced that we could gain any useful radiation effects information from the MDPH study, given its limitations.

NOV 30 1990

Hugh L. Thompson

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It is noteworthy that the MDPH report states that "based upon these results," MDPH will take four initiatives. These initiatives are to (1) require real-time monitoring of effluents, (2) impose more stringent release limits, (3) continue surveillance of cancer in the vicinity of Pilgrim, and (4) extend the study to include childhood leukemia if resources permit. The MDPH report offers no justification for these initiatives and, taken at face value, the MDPH report results suggest that the initiatives would provide no discernable improvement in public health and safety.

Within the limited scope of our review, we can find no support for the claim that any increase in the expected number of cases of leukemia is linked with the Pilgrim plant operation, much less the claim of a 400 percent increase.

This review was conducted by Charles A. Willis and Thomas H. Essig of my staff.

IS/  
Frank J. Congel, Director  
Division of Radiation Protection  
and Emergency Preparedness  
Office of Nuclear Reactor Regulation

Enclosure: As stated

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NRC Staff Review of the Massachusetts Department of Health  
Study of Leukemia Near the Pilgrim Plant

I. Background

The NRC staff began a review in October 1990 immediately after receipt of the Massachusetts Department of Public Health (MDPH) report, Southeastern Massachusetts Health Study Final Report: Investigation of Leukemia Incidence in 22 Massachusetts Communities, 1978-1986 (October 1990)<sup>[1]</sup>. This health effects study was preceded by two others sponsored by the National Cancer Institute (NCI) (July 1990)<sup>[2]</sup> and the TMI Public Health Fund (August 1990)<sup>[3]</sup>, both of which were reviewed and summarized by the staff in a memorandum from James M. Taylor to the Commission, of September 14, 1990. Both the NCI and TMI studies found no relationship between observed cancers in the vicinity of nuclear power plants and the operation of the plants.

II. Approach Taken by the MDPH Study

The MDPH study was a retrospective case-control evaluation of leukemia [other than chronic lymphocytic (CL) leukemia], in residents of age 13 and above in the selected area. The "cases" involved the people in the area who had been diagnosed with non-CL leukemia between 1978 and 1986. The "controls" were selected from among other residents. The cases were paired with controls who were matched by age and sex but were otherwise selected randomly.

The MDPH researchers computed an "exposure score" for each person selected as a case or control. This exposure score is an index based on the fraction of time that each individual spent downwind\* and the distance between the

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\* As used in the MDPH study, this refers to the fraction of time during a year in which the wind was blowing from the plant toward the locations of interest (home and workplace).

Pilgrim plant and individual's home and workplace. The researchers compared the indices for the controls and cases. The extent to which the case's exposure scores were higher than the control's scores was considered the measure of whether the plant may have been the cause of the leukemia. Since no records of job and residence history were available, the researchers obtained the information needed to compute the exposure score from telephone interviews. Because nearly 90 percent of the people selected for cases and controls were deceased, relatives and friends were the source of most of this information.

There were several significant differences in the approach taken by the MDPH study when compared to the NCI study. The NCI study examined deaths from 16 types of cancer for adults and children, whereas the Massachusetts study examined incidences, not just deaths, and included only cases of leukemia for individuals 13 years of age and older. The NCI study recognized the importance of childhood leukemia (age 10 and under) and specifically examined the associated mortality data; the MDPH study did not address this age group. The NCI study covered a 35-year period and included 900,000 deaths in study counties and 1,800,000 deaths in control counties. The MDPH study covered a 9-year period and included 105 cases of leukemia and 208 individuals as controls. The NCI study compared data before and after start-up of nuclear facilities, whereas the MDPH study related cases to an exposure score (a function of the time spent downwind of, and the distance from, the plant).

#### 111. Staff Comments on the MDPH Study Report

The results of the MDPH study suggest that the incidence of leukemia for the more highly exposed individuals of age 13 and above in the area of the 22 towns may be 4 or more times the expected number of cases. This finding appears to conflict with the NCI study which, for the county in which the Pilgrim plant is located, found no increase in relative risk of leukemia for all age groups. In fact, the NCI study showed a slight decrease in relative risk after plant start-up, although this decrease was not statistically significant.

The MDPH report is replete with statements suggesting that the study may not be objective. For example, the first paragraph of the "Executive Summary" states that Pilgrim "had a history of emissions during the 1970s that were above currently accepted EPA guidelines...." No data to support this contention are offered. Although the releases in 1974 resulted in doses to a few individuals that may have exceeded the subsequent U.S. Environmental Protection Agency (EPA) guidelines, most of the population received doses much smaller, and during the other years in the 1970s, doses were at or within the EPA guidelines. Another example starts at the bottom of page 22 of the MDPH report. In that section, the report discusses the 1982 NRC citation of Pilgrim for major deficiencies in management controls without mentioning that the deficiencies were not related to effluent monitoring or control, and so did not affect emissions.

The report's references also suggest imbalance. Alarmist documents, even unpublished manuscripts and publications that have been discredited, are included, while the authoritative recent publications of the National Council on Radiation Protection and Measurement (NCRP)<sup>[4, 5]</sup> are ignored.

The contents of, and the omissions from, the report raise doubts concerning the technical validity of the study. The report does not contain either the data obtained or a full description of the methods used in analyzing the data. These omissions make a thorough review of the report impossible.

The most serious indication of bias is the failure to consider an important confounding factor. In a study of this type, radiation from other sources is an important confounding factor because the radiation doses from the plant emissions are small when compared to natural background. Further, the variations in lifestyles between individuals, such as the type of residence and travel habits, can result in doses greater than the doses received from plant effluents<sup>[4]</sup>. For example, the average external gamma doses from natural background varied as much as 40 mrem per year from one tract to another within 10 miles of the TMI reactors<sup>[10]</sup>. The report does not discuss this aspect of the problem. However, the report does acknowledge

that "...experts agree that commercial nuclear power plants in general contribute little in comparison to the other sources listed." The report further states that nationwide only 0.1 percent of population exposure to radiation is attributable to nuclear facility discharges. The report then states, "This [the 0.1 percent of exposure] should come as no surprise since commercial nuclear power facilities are engineered to comply with various regulations which limit release to small percentages of the total exposure." However, after making these correct statements concerning radiation exposure, the report introduces a biased viewpoint without providing a basis for or evidence to support the claim. The report states the following:

Demonstration of extraordinarily high releases is not absolutely essential for serious consideration of a hypothesized link between Pilgrim 1 and cancer; the questionable validity of currently accepted risk estimates would seem sufficient to generate interest in the relationship between even normal nuclear power plant operation and cancer.

This statement is incorrect because no change in the risk estimates can account for a discernable effect unless the doses from effluents are greater than variations in natural background dose. The dose question is addressed further in the next section.

Another major omission is noted in a recent review of the MDPH report by Professor Richard Wilson (October 1990) of Harvard University. He pointed out that earlier work had shown (1) communities in the eastern portion of Plymouth County (nearest the Pilgrim plant) have a leukemia incidence which is consistent with the State-wide data, and (2) communities somewhat further from the plant have a leukemia incidence which is significantly lower than the State-wide data<sup>[6]</sup>. Therefore, the question that should have been addressed by the MDPH study is why the leukemia incidence in the communities further from the plant is lower than the State-wide data, rather than the reverse situation.

#### IV. Staff Evaluation of Offsite Radiation Doses

To determine whether Pilgrim plant effluent releases could be associated with the excess cases of leukemia identified by the MDPH report, the staff used reported effluent release data<sup>[7]</sup> to calculate population doses and used BEIR V<sup>[8]</sup> risk estimators to evaluate the expected number of leukemia cases produced. The staff calculated population doses using standard methods<sup>[9]</sup> for the period from plant start-up (1972) through 1981. The total population dose estimated for this period for Plymouth County was 120 person-rem (the peak years were 1974, 40 person-rem; and 1977, 34 person-rem). This 120-person-rem dose was then taken to represent the total dose for the 22 towns (which is conservative, since the 22 towns are within Plymouth County). Using a risk coefficient of  $5E-5$  per rem for leukemia (10 percent of the total cancer risk of  $5E-4$  per rem), the number of cases of leukemia which may be associated with this population dose is estimated to be less than 0.01<sup>[9]</sup>. To place the 120 person-rem dose in proper perspective, it should be compared with the dose of approximately 234,000 person-rem that the residents of the 22 Towns received from natural background radiation, excluding the dose from naturally-occurring radon, during the same period of time.

The staff also calculated doses to the maximally exposed individuals. The hypothetical maximum annual dose, which accrued during 1974 at a location 1/4-mile west of the plant, was 34 mrem. The calculation assumes that a person was at this point 100 percent of the time for the full year, so it is unlikely that any real person received even half this dose. The 34 mrem dose was only 7 percent of the limit in effect at the time and, with reasonable allowance for time away from the site boundary, it would not exceed the present EPA limit of 25 mrem in a year. The 34-mrem dose does exceed the current NRC criteria established in the Pilgrim radiological effluent technical specifications.

The total dose calculated for the maximally exposed individual(s) for the full 9-year period was approximately 100 mrem. Assuming an average dose of



100 mrem per year from natural sources, even the maximally exposed individual would have received no more than about 10 percent of his total radiation dose from effluents released from the Pilgrim plant.

The fact that doses from Pilgrim effluents were small in comparison to doses from natural sources invalidates the MDPH study. Because radiation doses were predominantly from natural sources, the determination of doses solely on the basis of distance from the plant is an invalid approach.

Therefore, the distribution of leukemia incidence around the plant can provide no information about the biological effects of radiation. Even if all leukemia were caused by radiation, the effects of the small doses from Pilgrim effluents would be hidden by the effects of variations in doses from natural radiation and lifestyles.

#### V. Initiatives

The "Executive Summary" of the MDPH report states that, as a result of the study, four initiatives will be taken. The initiatives are to (1) implement real-time monitoring of radionuclide emissions, (2) impose more stringent release limits, (3) continue surveillance of cancer in the Plymouth area, and (4) extend the study to include childhood leukemia if resources are available.

It is interesting that the MDPH report offers no justification for these initiatives. Furthermore, these initiatives do not appear to be capable of producing any health and safety benefit. For example, real-time effluent monitoring would not significantly improve our ability to determine offsite doses because the uncertainties in releases are already far smaller than those caused by other factors such as the behavior of the local populace and the impact of local micrometeorology. More stringent release limits also seem unjustified because the NRC has already lowered the release limits from those in effect during the period of the study by a factor of 10 for noble gases, and the resulting doses are negligible compared to the doses from natural sources.

VI. Conclusion

The staff estimated the population dose (120 person-rem) for the period 1972 through 1981 for the 260,000 individuals residing in the 22 towns. This estimate adds less than 0.05 percent to the natural background radiation dose (not including naturally-occurring radon). The less than 0.01 cases of leukemia that the staff calculated using BEIR V risk estimators and the 1972-81 cumulative population dose (120 person-rem) would not be discernable. This statement would be valid even if, as claimed in the MDPH study, the "questionable validity of currently accepted risk estimates" implied an underestimate of the true risk by a factor of 10-100. Even the dose to the maximally exposed individual was increased less than 10 percent by Pilgrim effluents. The staff cannot find any support for the claim that an increase in the expected number of cases of leukemia is linked with the Pilgrim plant operation, much less the claim of a 400-percent increase.

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